REMARKS

These amendments and remarks are in response to the Office Action mailed April 1, 2005. Claims 1,9,10 and 12 have been amended to define Applicants' invention. Claims 1, 3 and 9 and 12 are free of the prior art, and theory § 112 objections are resolved below. Accordingly, these claims are in condition for allowance.

Objection Maintained

Regarding paragraph 6, Applicants will submit the required formal drawings upon the receipt of the Notice of Allowability.

Objection(s)

The Examiner states in paragraph 14 that claims 3 and 11, and claims 9 and 12 are duplicate claims encompassing the same scope. Dependent claims 11 and 12 have been amended to depend from independent claim 10, instead of claim 1. Applicants respectfully request withdrawal of this objection.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

In paragraph 12 of the 04/01/05 Office Action, the Examiner finds no descriptive support in the specification, as originally filed, for an ALS1 protein comprising or consisting of 'SEQ ID NO: 7' and that the 06/21/04 amendment introduced 'SEQ ID NO: 7' to be a polynucleotide as opposed to a protein. (page 6, line 10 of the specification).

Applicants refer the Examiner to Figure 7 in the original specification where both the nucleotide and polypeptide sequence for ALS1 is provided. The Sequence Listing separates these sequences into nucleotide (SEQ ID NO. 7) and polypeptide (SEQ ID NO. 8). Applicants also refer Examiner to the specification on p. 18, lines 14-16 for definition of the N-terminal fragment: "Example 3. ...PCR was used to amplify a fragment of ALS1, from nucleotides 52 to 1296. This

1246 bp fragment encompassed the N-terminus of the predicted ALS1 protein from the end of the signal peptide to the beginning of the tandem repeats." (p. 18, lines 14-16). The present claims are amended to clarify the identity of the sequence in each instance.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

The Examiner states in paragraph 13 of the 04/01/05 Office Action that claims 1,3, 9, 11 and 12 are indefinite for failing to particularly point out and distinctly claim the subject matter of Applicants invention.

As originally filed, Figure 7 contains both the polynucleotide sequence with the corresponding amino acids for the polynucleotide sequence designated under the polynucleotide sequence. The Sequence Listing later filed by Applicants disclosed SEQ ID NO 7 for the nucleotide sequence and SEQ ID NO 8 for the poly nucleotide sequence of ALS1. In the Office Action response of 04/09/03 (see page 4), the following sentence was added on page 18, line 20 through page 19, line 7: "The underlying polynucleotide sequence and the polypeptide sequence of ALS1 are [is] listed in Figure 7 (SEQ ID NOS: 7 and 8)." (insertion grammar indicated).

As noted above, Applicants have reviewed the claims for proper referral either to nucleotide (SEQ ID NO. 7) and protein (SEQ ID NO. 8), and have amended the claims accordingly.

Taking the Examiner's remarks of paragraph 13 in order:

(a). Examiner states that claim 1 stating : "ALS1....protein (SEQ ID NO. 7) is indefinite because SEQ ID NO. 7 is a nucleotide. Applicants amend claim 1 to "ALS 1 ...protein (SEQ ID NO. 8 [7], which is the ALS1 polypeptide sequence.

(b). Examiner requests Applicants to specify that the recited SEQ ID number represents the nucleotide sequence, suggesting Applicants replace the recitation " SEQ ID NO:7" with "the

nucleotide sequence of SEQ ID NO: 7." Applicants have inserted the phrase "the nucleotide sequence" into claim 12.

(c). Examiner states that claims 9 and 12 lack proper antecedent basis in the limitation: "ALS1 protein, and suggests replacing the limitation with " the ALS1 protein." Applicants have amended claims 9 and 12 accordingly.

(d). Examiner states that dependent claim 12 is indefinite and confusing because independent claim 1 refers to ALS1 protein by SEQ ID NO. 7. Applicants have amended claim 1 to recite SEQ ID NO. 8, instead of SEQ ID NO. 7. Claim 12 is thereby correct in referring to the nucleotide sequence of SEQ ID NO. 7. Further, Applicants have inserted "the ALS1 protein" (insertion grammar indicated), as suggested by Examiner.

(e). Examiner states that claims 3, 9 and 11 are rejected as being indefinite because of indefiniteness identified in the base claim. As discussed in (a) above, Applicants have amended independent claim 1 to state SEQ ID NO. 8. This base claim now being correct, the dependent claims 3 and 9 can depend appropriately from claim 1. Claim 11 depends from claim 10, not claim 1, as discussed above in Objection(s). Applicants note that claim 12 refers to "the ALS1 protein" and narrows independent claim 10 by specifying "nucleotides 52 to 1296 of the nucleotide sequence of SEQ ID NO. 7." (insertion grammar indicated).

Having made the above clarifications, Applicants respectfully request the withdrawal of these indefiniteness rejections listed by the Examiner (paragraph 13 in the 04/01/05 Office Action) under 35 U.S.C. § 112, second paragraph for claims 1, 3, 9, 11 and 12.

Rejection under 35 U.S.C. § 102(b)

In paragraph 11 of the 04/01/05 Office Action, the Examiner rejected claims 10 and 11 as being anticipated by Hoyer *et al.* (1998) as evidenced by Harlow (1988). For reasons unrelated to

substantive patentability, Applicants hereby amend claims 10 and 11 to include the appropriate SEQ ID number to identify the recited N-terminal fragment. Claims 10 and 11 are not anticipated under 35 U.S.C. § 102(b) by Hoyer *et al.* (1998) as evidenced by Harlow (1988), because Hoyer *et al.* does not disclose every element of Applicant's invention as claimed. Applicants therefore respectfully request withdrawal of this 35 U.S.C. § 102(b) rejection for claims 10 and 11.

Anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226 (Fed. Cir. 1989) (See MPEP § 2131).

Taking Examiner's comments (04/01/05 OA, paragraph 11) in order:

The Examiner states that the instant rejection was not applied to claim 1, but to claims 10 and 11 (p. 4, line 4). Applicants note Examiner's statements regarding claims 1 and 3 (9/15/04 Office Action paragraph 11, p. 6:18) and claims 10 and 11 (09/15/04 Office Action paragraph 14, p.8:24) that Hoyer et al.'s enriched mixture is "sufficiently purified" to be included in a pharmaceutical composition. Applicants respectfully disagree. Applicants argued against this in detail in the 01/18/05 Response regarding both claim sets: 1 and 3; 10 and 11, and here again emphasize that the arguments presented in the 01/18/05 response apply to claims 10 and 11.

The Examiner states (paragraph 11, p. 4, line 5) that Claims 10 and 11 do not structurally identify the recited N-terminal fragment by a SEQ ID number. Applicants amend claims 10 and 11 to refer to the proper sequence identification number for both claims 10 and 11.

The Examiner (paragraph 11, p. 4, line 16) refers to reasons for rejection of claims 10 and 11 previously set forth in detail at paragraph 14 of the 09/15/04 Office. In this paragraph 14, the

Examiner states, "...that due to multiple purification steps, Hoyer's isolated N-terminal fragment is sufficiently purified (emphasis added) for inclusion in a pharmaceutical composition. The purified, dialyzed and concentrated final prior art N-terminal fragment product contained in PBS qualifies as a pharmaceutical composition (emphasis added) consisting essentially of a biocompatible carrier and an isolated and purified N-terminal fragment of ALS1 obtained from *Candida* albicans, as recited." Applicants respectfully disagree.

The Examiner states (09/15/04 Office Action, paragraph 14, p. 8:24) that Hoyer's N-terminal fragment dialyzed against PBS is "sufficiently purified" for inclusion in a pharmaceutical composition." This statement lacks supporting scientific evidence, and is speculative at best. As requested previously in their 01/18/05 Response, Applicants request that the Examiner support this statement (09/15/04 Office Action, paragraph 14, p. 8:24) with a showing.

Hoyer *et al.* (1988) had a mixture of proteins dialyzed against PBS enriched in ALS1 N-terminal fragment, but did not have an isolated and purified preparation of N-terminal fragment of ALS1 protein. Because the polypeptide of interest in Hoyer *et al.* is associated with a mixture of other proteins in PBS, the polypeptide of interest is not "isolated and purified" as claimed by Applicants. The standard of "isolated and purified" is not met for the protein of interest. To use an enriched mixture of proteins as immunogen, such as the Hoyer *et al.* enriched mixture, is not acceptable immunological procedure, and on its face, would not be the "isolated and purified" pharmaceutical composition as claimed. The standard under § 102 requires a clear and unequivocal disclosure of each element of the claim. Therefore, the claimed element of "isolated and purified" is not disclosed by Hoyer *et al.* (1998) and the § 102(b) rejection cannot be maintained for claims 10 and 11. Applicants, on the other hand, have demonstrated the usefulness of a pharmaceutical

composition of an acceptable biocompatible carrier and an isolated and purified preparation of the N-terminal fragment of ALS1 protein.

To summarize, since claims 10 and 11 have been amended to include a structural limitation that clearly is not disclosed by Hoyer *et al.* (1988), these claims cannot be anticipated by the enriched mixture product of Hoyer *et al.* (1988). Hoyer et al.'s enriched mixture of proteins in PBS does not anticipate the isolated and purified pharmaceutical composition as claimed by Applicants. Applicants therefore respectfully request withdrawal of this rejection under 35 U.S.C. §102(b) for claims 10 and 11.

With this amendment, Applicants submit claims 1, 3, 9 –12 are in condition for allowance, and respectfully request a Notice of Allowance.

Applicants believe that no fee is due, however, applicants' attorney of record hereby authorizes the Commissioner to charge any amounts due in the above-identified application to Orrick, Herrington & Sutcliffe's Deposit Account No. **150665** and to credit any overpayments to said Deposit Account No. **150665**.

Respectfully submitted,

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